



GALIX

BIOMEDICAL INSTRUMENTATION, INC.

GALIX ECG Professional Station

GALIX ECG-PS

COMPUTERIZED ELECTROCARDIOGRAPHY



FDA – Section 5 Operation Manual

*Version 2.2
March 1, 2003*

**GALIX BIOMEDICAL INSTRUMENTATION
2555 Collins Avenue, Suite C-5
Miami Beach, FL 33140, U.S.A.
Tel.: (305) 534-5905 Fax : (305) 534-8222**

Index

1. INTRODUCTION	3
2. ECG PROFESSIONAL STATION	4
2.1. CARRYING OUT THE ECG EXAM.....	5
2.1.2. ADVANCED LOOK OF PATIENTS OF AND ATTENDANTS.....	6
2.1.3. VIEW OF DETAILS OF PATIENTS AND ATTENDANTS.....	7
2.1.4. ADD A PATIENT / ATTENDANTS TO THE DATABASE.....	8
2.2. ECG EXAM SCREEN ELEMENTS.....	9
2.2.1 OPTIONS MENU: VIEW.....	12
2.2.2 EXAM IDENTIFICATION INDICATORS.....	12
2.3 CONTROL PANEL.....	13
2.4 POSITION CONTROL ON REVIEW SCREEN.....	14
2.4.1. NEW POSITION WINDOW.....	14
2.5. CONTROL BARS OF THE CHANNEL.....	15
2.6. MONITORING CONTROL.....	17
2.7. TOOLS ICONS.....	17
2.8. REGISTER CONTROL.....	17
2.9. CALIPER.....	20
2.10. CHANNELS LIST.....	21
2.10.1 CHANNEL LIST IN THE MONITORING SCREEN.....	22
3. ASSIGNMENT OF CONTROL KEYS	24
4. TECHNICAL SPECIFICATIONS	25
5. WARRANTY	27

1. INTRODUCTION

The *GALIX ECG-PS* is a PC Driven Electrocardiograph and Stress Test system, real time 12 lead, capable to monitoring, analyze store and print ECG patient exams. The system meets most of the present and future needs of the cardiology clinician.

The *GALIX ECG-PS* will present high-resolution images of a patient's ECG exam and stores the exam in the memory for future reference or analysis. The attendant can select to change lead derivations, gain, time, etc. All essential commands are available through menus, buttons or keystrokes.

The *GALIX ECG-PS* measures cardiac rate and other basic parameters, indicates bradycardia and tachycardia events by visual and audible means. All relevant information, date, time, etc, is presented in the screen.

The *GALIX ECG-PS* is based on a hand held Data Acquisition Module (USB-DAM) with a computer interface USB connector, that acquires high resolution ECG and sampling rate. Patient cables are connected directly to this module. The USB connector will connect to any USB port in a laptop or desktop PC. The module obtains power through the USB port eliminating the need for an additional power converter or external power supply.

The software used by the *GALIX ECG-PS* will present computerized normal ECG and Stress Test Studies. The *GALIX ECG-PS* will operate under Windows 98 or greater. Below are some of the characteristics of the program.

- Simultaneous monitoring and printing of standard 12 lead ECG or lead combinations pre selected by the attendant
- Different selectable presentation formats
- Selectable Amplitude Scales (5, 10 or 20 mm/mV)
- Selectable Scan Rates (25, 50 or 100mm/s)
- Heart Rate measurements in the 30 -240 bpm range
- Automatic selection of J Point and ST segment
- Standard and programmable stress test protocols
- Able to control peripheral equipment (treadmill, bicycle, etc)
- Time and amplitude measurements by cursors in the screen

The Galix ECG–PS offers different print formats including Number of leads per page (1, 2, 3, 6, or 12) and gain (x1, x1.5 or x2). The printouts includes name of patient, date, hour, etc, for ease identification. It is also possible, in some formats to include complete demographic data, commentary and interpretation.

All ECG registries may be stored in a PC hard disk for further analysis or revision. These exams will form an ECG database that includes all commands for each patient with ease; Add, Delete, Search, etc.

Due to the high detailed screen resolution and sampling rate, the system will allow full morphological analysis. The attendant is able to obtain intervals, amplitudes with cursors in the screen besides the automatic measurement capacity of the software.

STRESS TEST

This function of the *GALIX ECG-PS* will provide patient stress testing from 3 to 12 leads using standard preprogrammed protocols (Bruce, Bruce Modified, Naughton, Astrand, etc) or protocols designed by the user.

The *GALIX ECG-PS* screen will display different stages (speed, elevation or load), time elapsed, and suggestions and warning messages to guide the attendant during the exam. During the exam an automatic register at each stage will record the ECG, cardiac rate, ST segment and ST slope. All information is presented at the final exam printout.

The final Exam printout will include the following information:

- Demographic Patient information
- Table presenting for each stage: duration, load, heart rate, systolic pressure, diastolic pressure, mean pressure, tension, time, index and comments.
- ECG tracings and ST segment trends.

The complete Stress Test exam may be stored in the PC Hard disk. Individually these are identified for future retrieval and further analysis. The number of studies stored is limited only by the capacity of the PC's hard disk.

WARNING:

The USB-DAM acquisition module of the ECG-PS system provides complete electric insulation of the patient conform to the IEC 60601 standard. Anyway, some personal computers and printers have a strong current discharge to earth. If the connection to earth of the computer opens accidentally and the attendant is in simultaneous contact with the patient and with the metallic parts of the computer, it is possible that the patient receives a discharge through the attendant. This situation is highly improbable in the standard operating procedure. Anyway, if the stretcher/examination bed and computer layouts make this possible, it is an obligation to have a security insulation transformer between the mains connection and the Computer/Printer equipment.

2. ECG PROFESSIONAL STATION

This is the main program to obtain an ECG study.

2.1. TAKING THE ECG STUDY

Start

1. Turn on the PC. Automatically a Windows screen named Desktop will appear with all the control icons.

Double click the “*GALIX ECG-PS*” program and Figure 1 will appear:

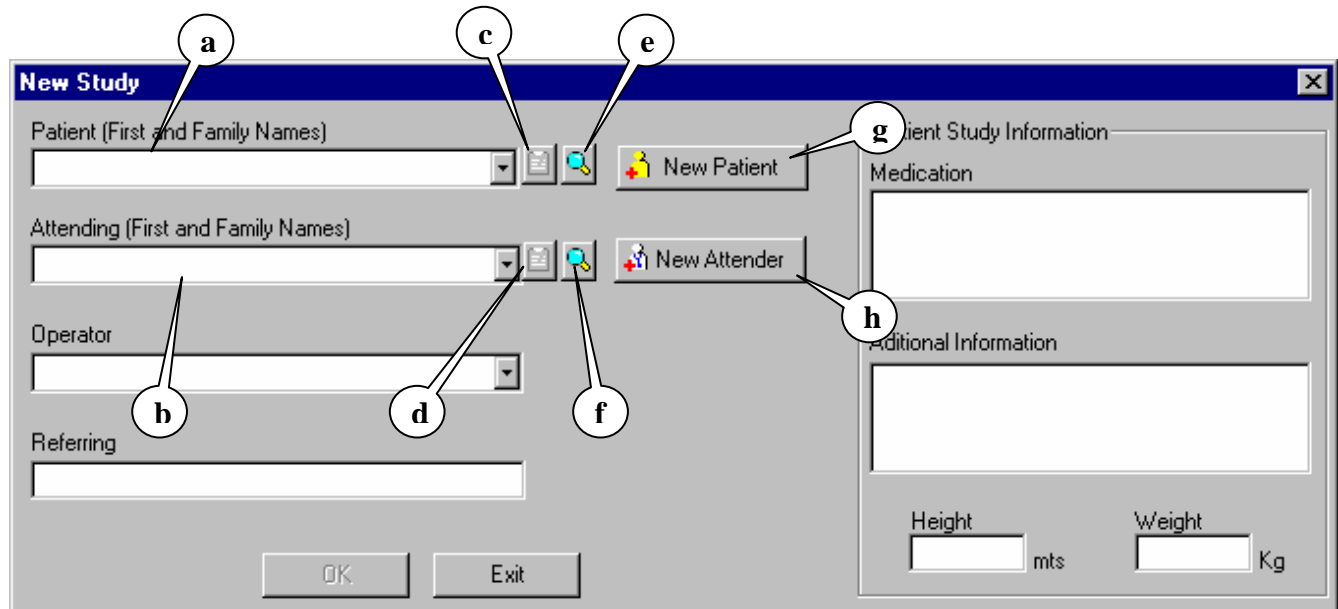



Figure 01

If the patient is a new one, write the name of the patient and click on (g-New Patient) to complete Patient Data. This patient will be added to the existing Patient Data Base. If the patient to be examined is already included in the DB, use TAB to locate the patient's name.



Click on the attendant Line (b) or use TAB to choose the current physician. If the Current attendant is not listed, enter it. This name will also be added to the attendant's Data Base.

Once the patient and attendant are entered or selected, click on OK to open the Monitoring Screen on Figure 06. This screen will only be activated once the patient and attendant are entered or selected.

2. Click the  button in the Scan toolbar (**Figure 07-e**) to start the scan.

Stop:

To stop the ECG acquisition:

1. Select **SCAN** in the user menu (**Figure 07-h**) and select the **STOP** option. Answer Yes to the question to confirm the scan stop. The stop option can also be called with the  button (**Figure 07-e**) placed in the Scan Toolbar.
2. In order to save the study in the database, click the disk icon in the Toolbar.
3. To quit the *ECG – PS* software, click the  button in the upper right corner of the window. If changes are not saved a warning message will be shown.

NOTE: Before quitting the software, the ECG acquisition must be stopped.

2.1.2. ADVANCED PATIENT AND ATTENDANT SEARCH

In this window the user can easily search a patient or an attendant. The search can be done by ID, name or both.

To make a search:

- a) Click the advanced search button (see **Figure 01-e and f**). The Advanced Search dialog will appear (see **Figure 02**).
- b) Type the ID and patient name in the corresponding fields (**Figure 02-a and b**). For a broader search leave one of the fields empty.
- c) Click the Search button (**Figure 02-c**).
- d) The results will be displayed in the Results Grid.
- e) If the Patient or the Attendant is in the list of the Result Grid, select it by clicking on that row.
- f) To use the selected Patient or Attendant in the study, click the Select Patient button. (**Figure 02-d**).
- g) To cancel the search simply press the Cancel button (**Figure 02-e**).

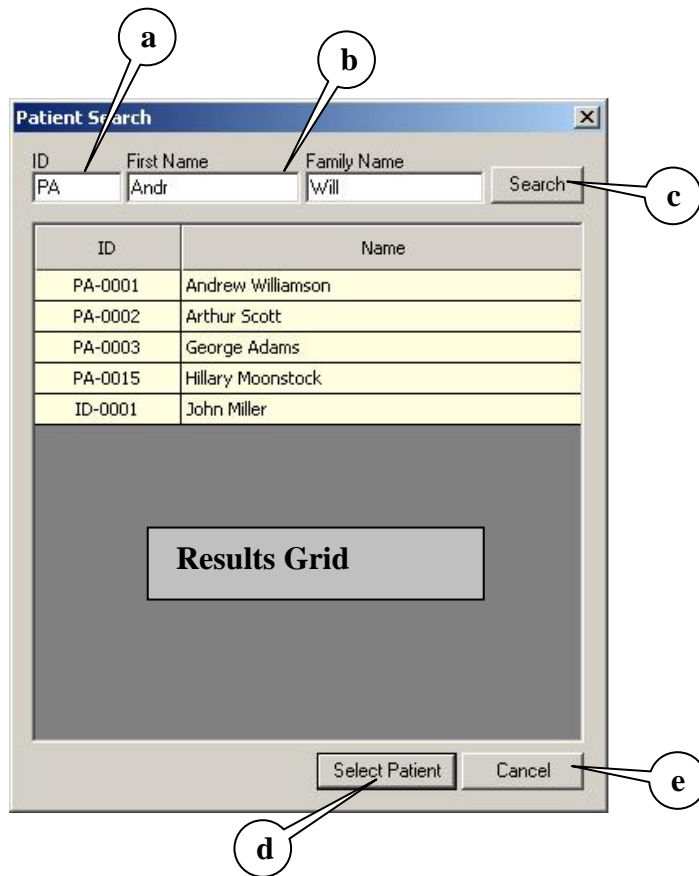


Figure 02

2.1.3. PATIENT AND ATTENDANT DETAILD VIEW

Once selected the Patient or the attendant the user can click the View Details button (see **Figure 01-c and d**) . This button will open a dialog with the Patient or Attendant information stored in the database (see **Figure 03**).

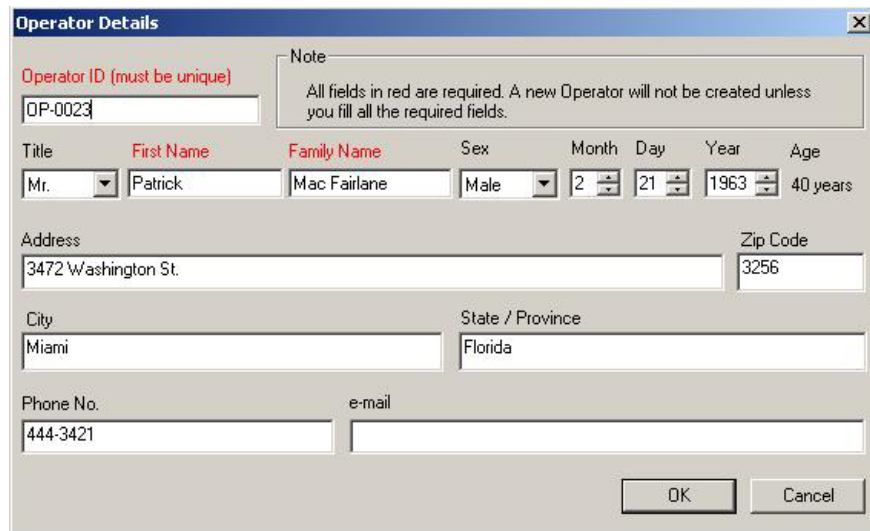


Figure 03

2.1.4. ADD A PATIENT OR AN ATTENDANT TO THE DATABASE

If the Patient or the Attendant is not in the database, the user can add them by clicking on the New Patient or New Attendant Button (**Figure 01-g and h**).

To add a Patient:

- Click on the New Patient button. The New Patient dialog will be displayed (see **Figure 04**). If the button is disabled, the selection must be deleted in the Patient field (**Figure 01-a**).
- In this dialog the fields with red title must be completed to add the patient to the database. The ones titled in black are optional.
- Click on the OK button. The dialog will close and the Patient will be added to the database, and selected in the Actors dialog.
- To cancel the operation click on the Cancel button.

The screenshot shows a 'New Patient' dialog box with the following fields and values:

- Patient ID (must be unique):** ID-0001
- Note:** All fields in red are required. A new Patient will not be created unless you fill all the required fields.
- First Name:** John
- Family Name:** Miller
- Sex:** Male
- Month:** 2
- Day:** 14
- Year:** 1971
- Age:** 32 years
- Nationality:** (empty)
- Profession:** (empty)
- Address:** 2555 Collins Avenue
- Zip Code:** 33456
- City:** Miami
- State / Province:** Florida
- Phone No.:** 555-5643
- Fax:** 555-5644
- e-mail:** (empty)

Buttons: OK, Cancel

Figure 04

To add an Attendant:

- Click on the New Attendant button. The New Attendant dialog will be displayed (see **Figure 04**). If the button is disabled, the selection must be deleted in the Attendant field (**Figure 01-b**).
- In this dialog the fields with red labels must be completed to add the Attendant to the database. The ones titled in black are optional.
- Click on the OK button. The dialog will close and the Attendant will be added to the database, and selected in the New Study dialog.
- To cancel the operation click on the Cancel button.

New Operator

Operator ID (must be unique)

Note
 All fields in red are required. A new Operator will not be created unless you fill all the required fields.

Title **First Name** **Family Name** Sex Month Day Year Age
 Dr. Jonas Auchtung Male 11 7 1961 41 years

Address Zip Code
 3417 Lincoln Avenue 4456

City State / Province
 Miami Florida

Phone No. e-mail
 444-6734

OK Cancel

Figure 05

2.2. ECG SCREEN ELEMENTS

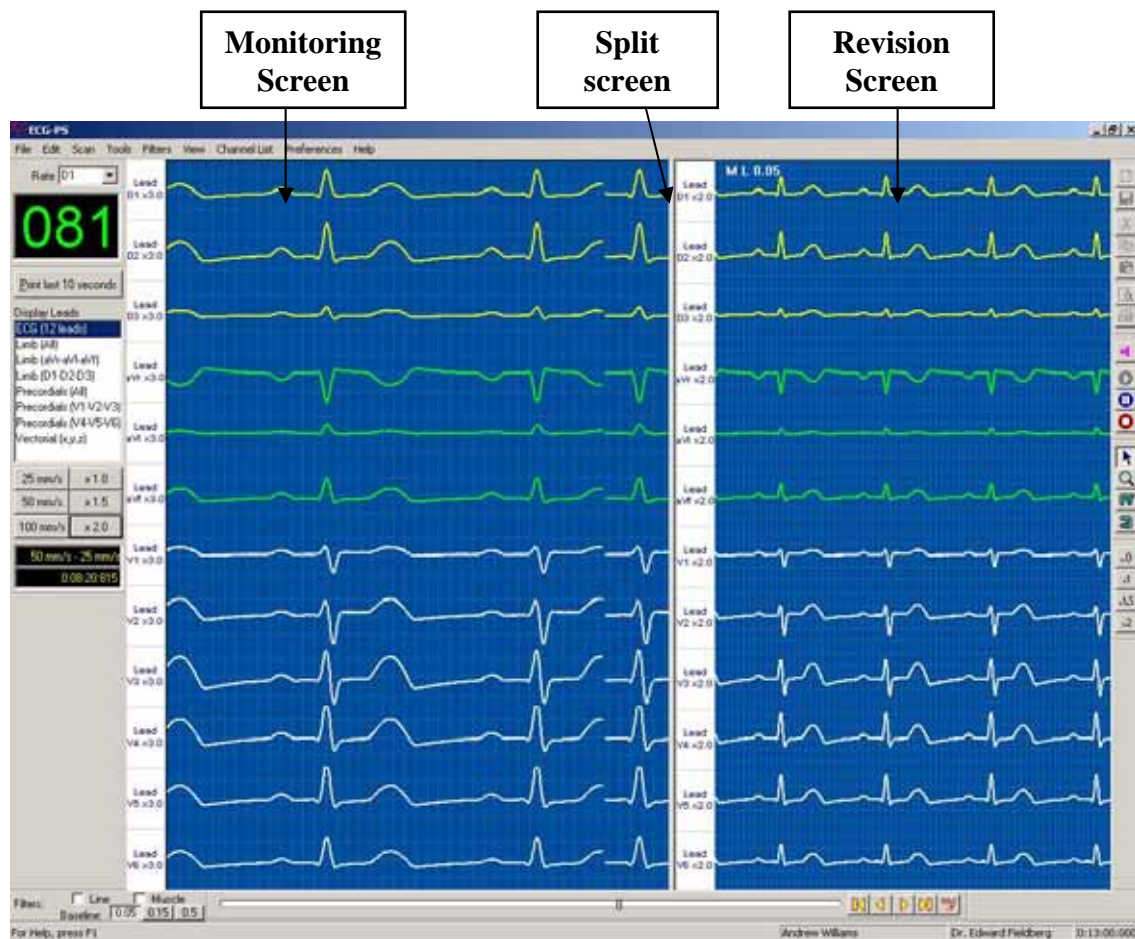


Figure 06

MONITORING SCREEN (Left Side):

Exhibit real time ECG signals.

REVIEW SCREEN (Right Side):

Allows a complete study review of the exam being done.

SPLIT SCREEN BAR

Divides the screen into 2; monitoring and review screens. The size of each can be changed by the attendant by clicking on the bar with the mouse and moving the line.

IMPORTANT: Do not eliminate the screens. Leave at least 2 to 3 mm of the Split bar. It will be easier to resize the screen later.

FILTERS:

The attendant can introduce the following filter at any time during the exam.

- **Line:** To minimize the interference generated by the power line (50 or 60 Hz, as it is specified in the system configuration).
- **Muscular:** To minimize the interference generated to the ECG by myoelectric potentials noise.
- **Baseline:** To minimize the interference generated by skin-electrode interface to the ECG Baseline.

The following controls are available during the ERGO exam:

- a) *Control Panel*
- b) *Position Control*
- c) *Channel bar in the Monitoring Screen*
- d) *Channel bar in the Review Screen*
- e) *Monitoring Control*
- f) *Tool Icons*
- g) *Print Control*
- h) *Option menu*
- i) *Filters*
- j) *Heart Rate Meter*
- k) *Position Bar*
- l) *Gain Control in the Review Screen*

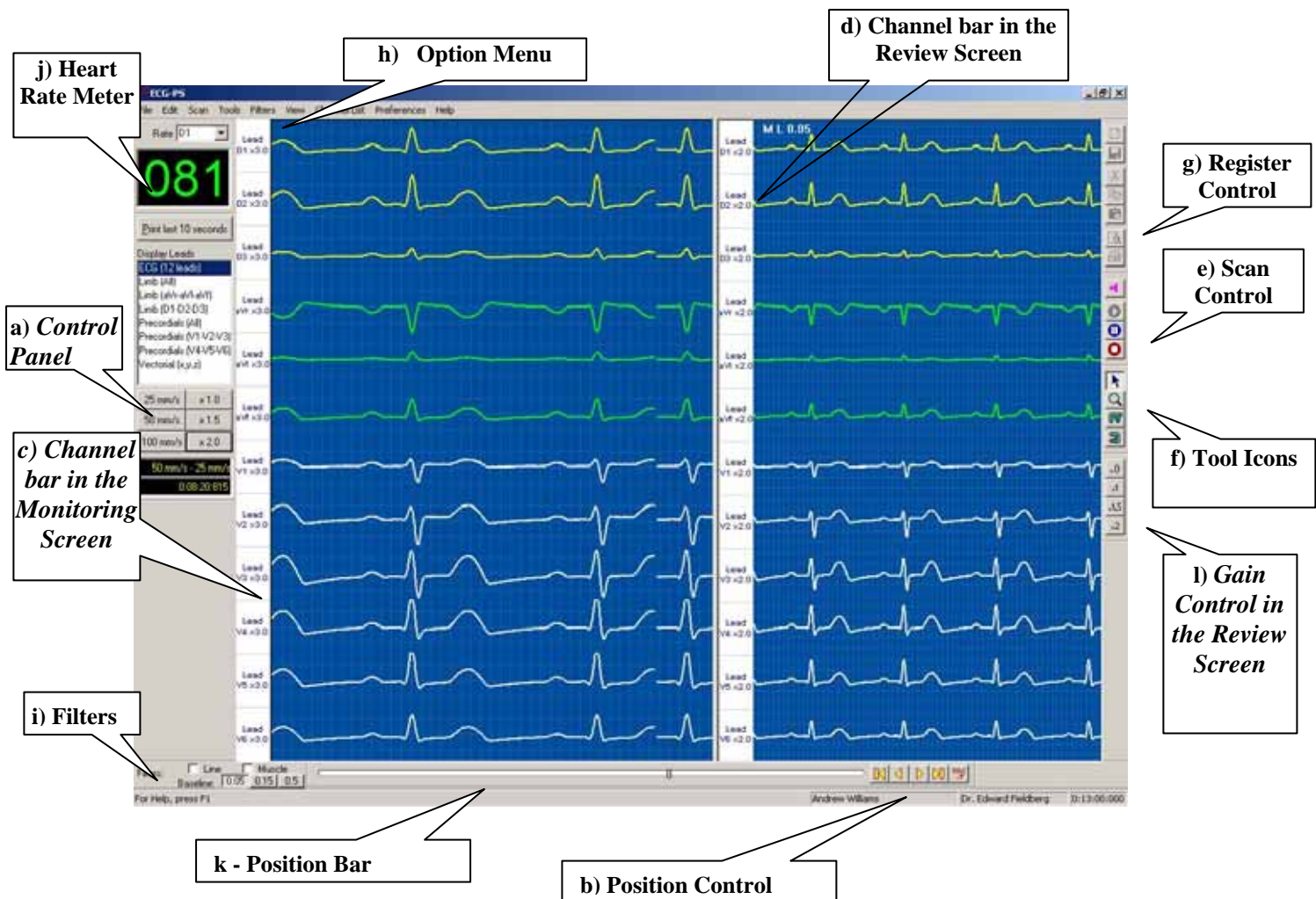


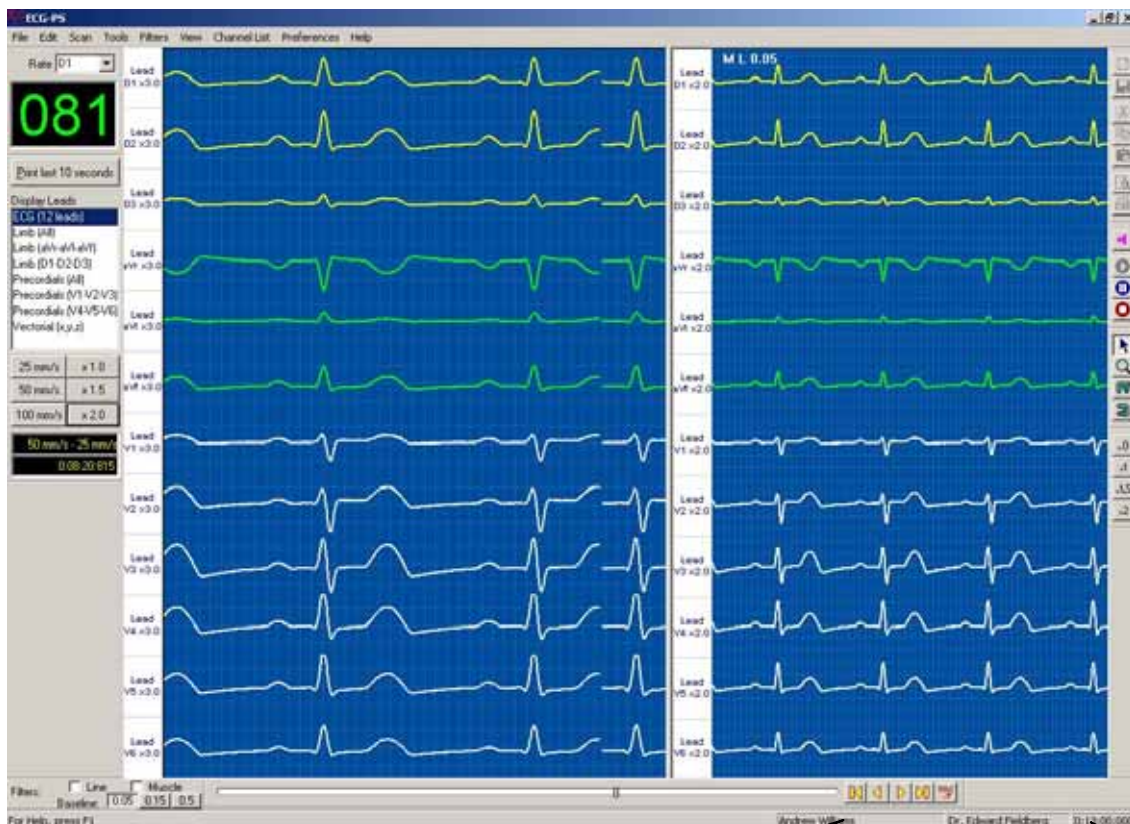
Figure 07

2.2.1 OPTIONS MENU: VIEW

Within the Options Menu (Figure 07-h), a “View” icon is available, allowing to the attendant the following options:

- **Tool Bars:** Makes the tool bar visible
- **Status Bar:** Makes the status bar visible
- **Scan Window Channel Bar:** Makes the channel bars visible in the scan screen
- **Review Window Channel Bar:** Makes the channel bars visible in the review screen
- **Scan Window Grid:** Make the grid lines in the scan screen visible
- **Review Window Grid:** Make the grid lines in the review screen visible
- **Tag List:** Presents a list of all events captured during the exam
- **Black Background:** Changes the background color, leaving the last color selected.
- **Line Thickness:** Permits a change of line thickness. This option is useful for making slide presentations.

2.2.2 PROCESS INDICATORS



1) Patient's name

2) Attendant's Name

3) Elapsed time during exam

2.3 CONTROL PANEL

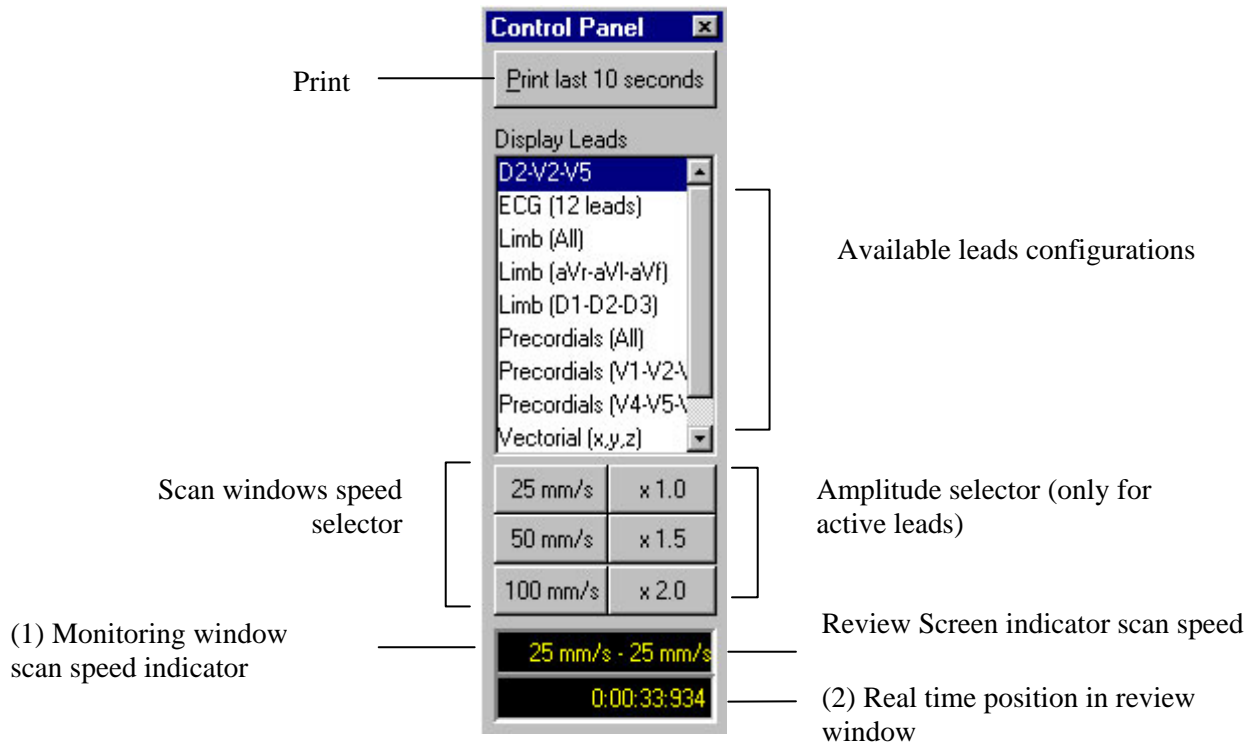


Figure 09

PRINT (See **Figure 07-g**)

By clicking on this button begins the printing of the ECG signals shown in the screen.

IMPORTANT: The monitoring window must be in PAUSE condition.

PRINT LAST 10 SECONDS:

Pressing this button the last ten seconds will be instantly printed.

CONFIGURATIONS

List of leads configurations available.

SPEED

25- 50- 100: The scanning speed is rated in mm/sec.

AMPLITUDE

1 – 1.5 – 2: General gain of every ACTIVE channel.

DISPLAYS

(1) Indicates the scanning speed in the monitoring and review windows.

(2) Presents the position in minutes and seconds of the review window. The position can be modified with the cursor of the position control. (**Figure 10**).

2.4 POSITION CONTROL IN THE REVIEW SCREEN




(a)

Figure 10







(b)

The position control in the **Review Screen** allows the quick location of any time in the study.

The cursor  is used to displace the different electrocardiographic images of the **Review Screen** along the study. The process consists in positioning the arrow of the mouse upon the cursor, click on it with the left button and drag the mouse. The real time of the position of the cursor in minutes and seconds upon the screen it is indicated in the lower window of the CONTROL PANEL. (Figure 09-2).

Additional possibilities to locate the ECG signals in the review screen:


Available by clicking on the left button of the mouse. (See Figure 10):

- To the left of the cursor it forwards 4 seconds (a).
- To the right of the cursor it rewinds 4 seconds (b).
- : Translates the image to the beginning of the study.
- : Translates the image to the end of the study.
- : Rewinds the image 250 ms.
- : Forwards the image 250 ms.
- : Opens the New Position window (See Figure 11)
- : Opens Tag List window (Figure 07)

The New position and Capture windows are explained below:

2.4.1. NEW POSITION WINDOW

This window provides a quick access to any moment in the study by an easy introduction of the values in minutes and seconds of the new event. The signals corresponding to the time selected are shown in the review screen. Lately, the user will be able to displace the image forwards or backwards using the commands explained before.

We access to the New Position window by clicking on the button  of Figure 07.

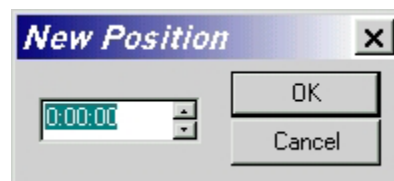



Figure 11

IMPORTANT: Fill the time of New Position according to the assigned digits.

<u>MINUTES:</u> two digits	<u>SECONDS</u> two digits
--------------------------------------	-------------------------------------

The time entered is valid by pressing . The review screen will show the signals corresponding to the selected hour.

2.5. CHANNEL CONTROL BARS

The channel control bars are located to the left of the monitoring and review windows (**Figure 15**). They can be hidden independently from the option of the View menu by selecting Scan Window Channel Bar and Review Window Channel Bar respectively.

Indicates for all the channels:

- (a) Channel signal identification.
- (b) Channel Gain (amplitude).
- (c) Selected Channel. By clicking on a particular channel it displays a dialog box with the properties of the channel. (**Figure 16**). The background of the selected channel will be shown in orange for a clear identification of it.

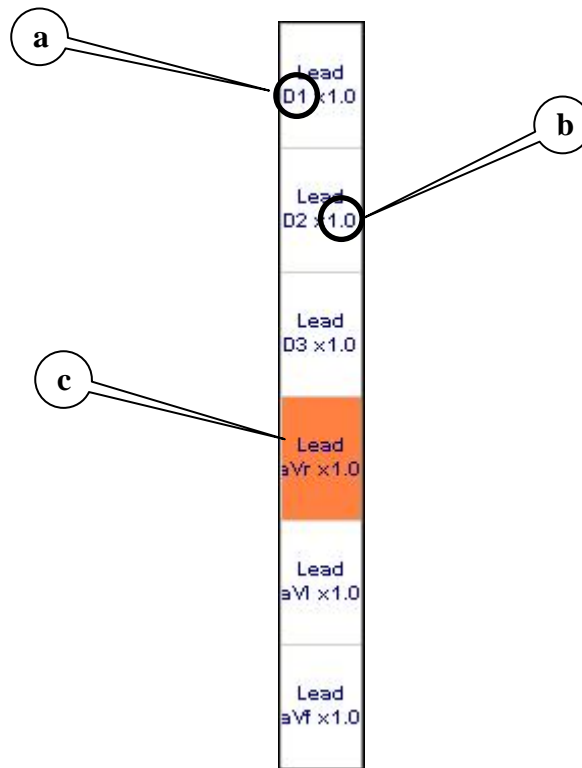
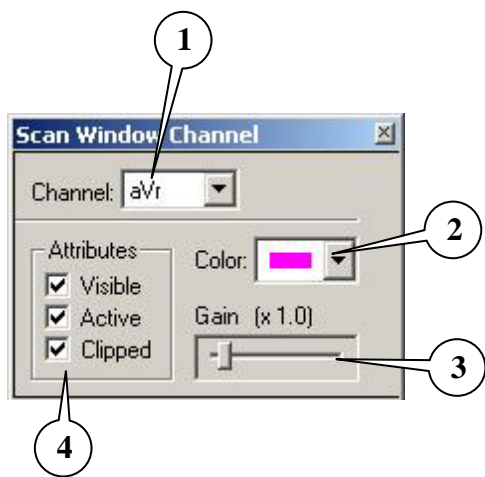


Figure 15



- (1) Identification of the selected derivation
- (2) Displays to choose the color of each derivation
- (3) Modifies the amplitude of the selected derivation
- (4) Attributes of the selected derivation

Figure 16

The CONTROL CHANNEL window presents the following command options:

(1) CHANNEL:

- Clicking on this line will show all the derivations available from the selected configuration.
- By clicking on one of this derivations automatically will change it.

(2) COLOR:

- It is use to change the color of the derivation.
- Clicking on this box will show the pallet of colors to choose one.

(3) GAIN:

- Click on the cursor and move it to the right or left to increase or decrease the amplitude of the selected derivation.
- The new gain is also shown in digital format.

(4) ATTRIBUTES

VISIBLE:

- Click on this option to make the derivation visible or invisible in the screen. The rest of the derivations will relocate automatically.
- **IMPORTANT: besides the derivation is NOT visible, it's corresponding signal it's being process. In other words, the representation of the skipped derivation can be restore making it visible and reviewing again the study.**

ACTIVE:

- Active: The derivation is affected by the general gain of the CONTROL PANEL.
- Inactive: The derivation is not affected by the gain of the CONTROL PANEL.

CLIPPED:

- Yes: the peak of the signal will never invade the inferior or superior derivations.
- No: the peak of the signal can invade the inferior or superior derivations.

2.6. MONITORING CONTROL

This bar located on the right of the screen (See **Figure 07-e**) controls the following effects:

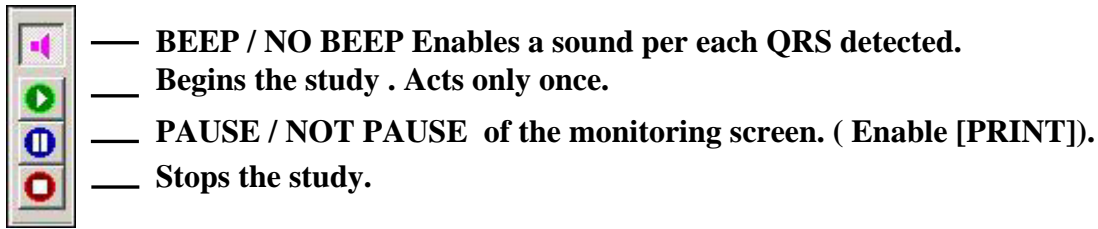


Figura 17

2.7. TOOLS ICONS

The following tools are available by clicking on the correspondent button:

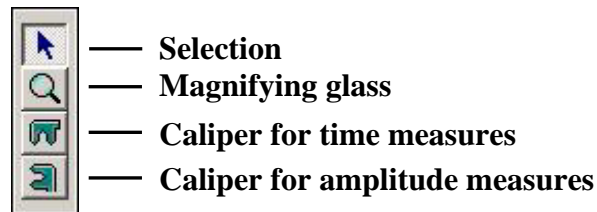




Figure 18

OBJECT SELECTION TO ACTIVATE OR MODIFY IT

- Click on .
- Select with the mouse the object you want to control and click it with the right button.
- Select with the mouse the tool you want to use and click it with the left button.
- Select with mouse the object you want to work with.

ZOOM

* This option changes the scanning speed in the screen you click on.

- Click on .
- Move the arrow of the mouse upon the monitoring or review screen (the arrow changes to a magnifying glass).
- Click on with the left button of the mouse to increase the scanning speed in the selected.
- Click on with the right button of the mouse to decrease the scanning speed in the selected screen.
- If the grid of the selected screen is activated, this one will change automatically in order to the new values of the scale.

CALIPER:

To activate the caliper you must click with right button on the screen that you want to work with . (See section **2.9 CALIPER**)

2.8. REGISTER CONTROL

The following icons activate the corresponding functions.

NOTE: It is recommended that the user get used with the basic commands of MS Windows in order to obtain maximum efficiency in the use of the following functions.

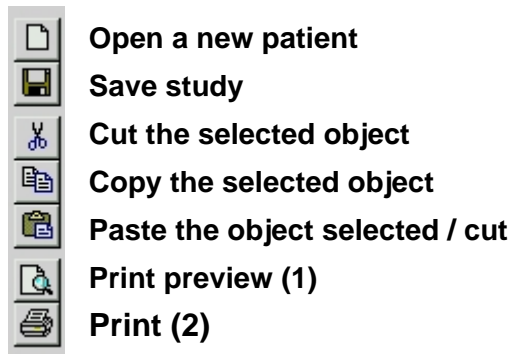


Figure 19

PRINT during monitoring it is possible to print the image with this button (See **Figure 19-2**). For it you need to click on PAUSE (See **Figure 17**).

Print Preview

After clicking in the icon “PRINT PREVIEW” (See **Figure 20**) the screen will show the page to print:

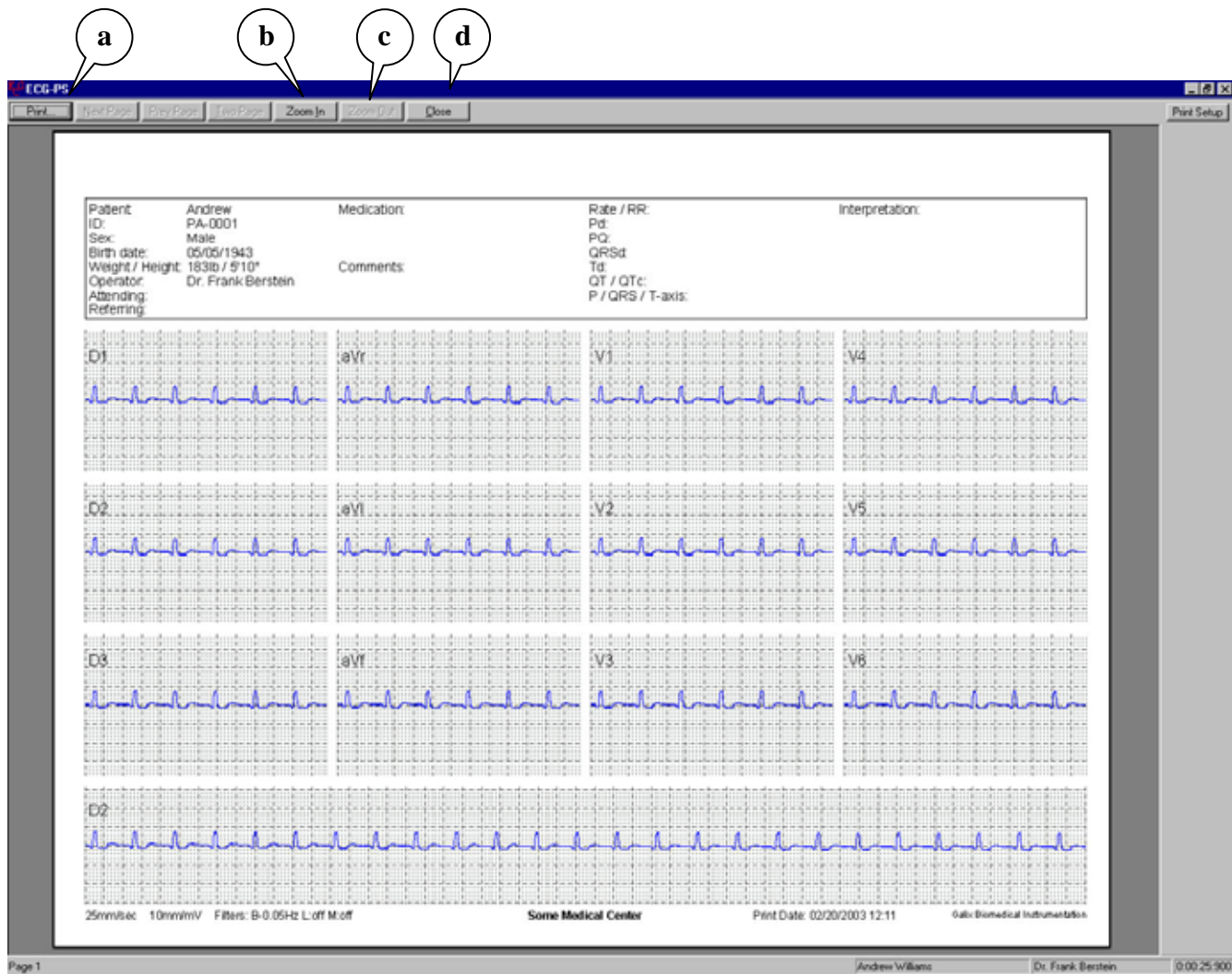


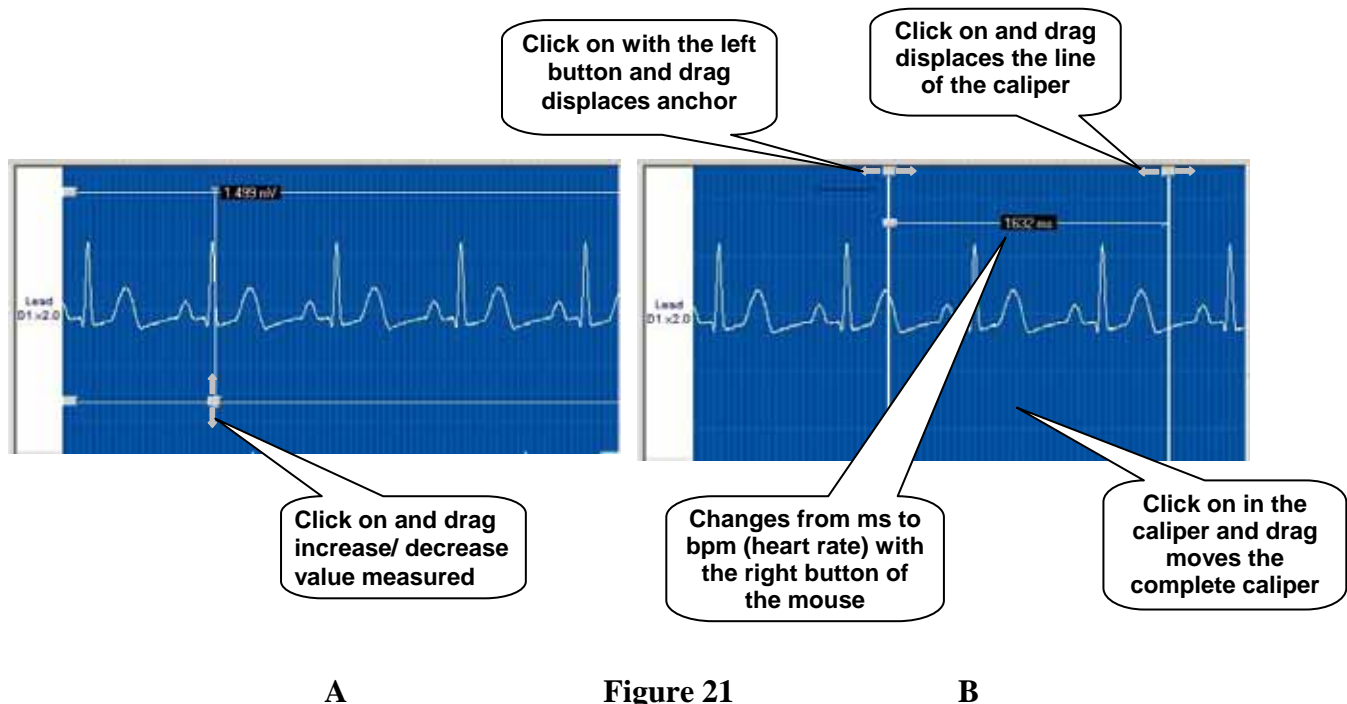
Figure 20

- (a) Click on **Print** to print the shown screen.
- (b) Click on **Zoom In** to enlarge the image. The arrow of the mouse will change to a magnifying glass. Point the area to enlarge. Click on **ZOOM** again to disable the function.
- (c) When **Zoom Out** is enabled, the image occupies more than a screen.
- (d) Press **Close** to close the window of Preliminary Presentation.

Note: If working with a color printer, all the objects and signals will appear with their correspondent colors.




2.9. CALIPER

The program allows the insertion of calipers to measure time (msec) and amplitude (mvolts) intervals of the ECG signal. The explanation given of one caliper is valid for the other one.



The number of CALIPERS to be inserted in both screens is limited.

Procedure to activate the calipers:

- Click on .
- Select with the mouse any of the screens and click on it with the right button.
- Click on  with the left button of the mouse.
- Select the screen and the arrow of the mouse will change into a .

Measurement:

The arrow of the mouse is .

- Click on the first point of the measurement and drag the mouse (maintaining the button pressed) to the second point of the measurement, then free the button of the mouse.



Observe that the digital value goes actualizing as the mouse moves. Moving it to the left will produce negative values.

IMPORTANT: Observe that pressing the right button of the mouse transforms the measurement indicated in milliseconds (ms) into beats per minutes (bpm)

Insert a new caliper:

The  tool will maintain active after inserting a caliper. To add another one follow the steps detailed before.

Erasing calipers:

- Point the caliper you want to erase with the  tool.
- Click on .
- If there is only one caliper it will be erased.
- If there were more than one caliper the following question will appear: Do you want to cut them all? The answer:
 - "YES" will erase all calipers from the screen.
 - "NO" Will erase only the selected caliper.

Note: Clicking the Paste button will recover the last caliper erased. (Figure 19).

Changing caliper color:

Select the caliper (square in the upper part of the caliper)

- Click on VIEW in the OPTIONS menu (Figure 07).
- Click on COLORS. A color dialog box will appear. (Figure 22).
- Click with the right button of the mouse the selected color.



Figure 22

2.10. CHANNEL LIST

The properties of the channels in the monitoring screen can be directly modified from the channels bars or from the channel lists. The second option allows the fast modification of any channel without going one by one.

2.10.1 CHANNEL LIST IN THE MONITORING SCREEN

To accede to the channel list of the monitoring screen (see **Figure 23 and 24**) you must select from the options menu (**Figure 06**), the Channel List option and then: Scan Window Channel List.

#	Lead	Label	Gain	Visible	Active	Clipped	Color
1	D1	Lead	1.0	✗	✗	✓	Red
2	D2	Lead	1.0	✗	✗	✓	Red
3	D3	Lead	1.0	✗	✗	✓	Red
4	aVr	Lead	1.0	✗	✗	✓	Magenta
5	aVl	Lead	1.0	✗	✗	✓	Magenta
6	aVf	Lead	1.0	✗	✗	✓	Magenta
7	X	Lead	1.0	✓	✓	✓	Yellow
8	Y	Lead	1.0	✓	✓	✓	Yellow
9	Z	Lead	1.0	✓	✓	✓	Yellow

Figure 23 – Vector Leads

#	Lead	Label	Gain	Visible	Active	Clipped	Color
1	D1	Lead	1.0	✗	✓	✓	Red
2	D2	Lead	1.0	✓	✓	✓	Red
3	D3	Lead	1.0	✗	✓	✓	Red
4	aVr	Lead	1.0	✗	✓	✓	Magenta
5	aVl	Lead	1.0	✗	✓	✓	Magenta
6	aVf	Lead	1.0	✗	✓	✓	Magenta
7	V1	Lead	1.0	✗	✓	✓	Green
8	V2	Lead	1.0	✓	✓	✓	Green
9	V3	Lead	1.0	✗	✓	✓	Green
10	V4	Lead	1.0	✗	✓	✓	Green
11	V5	Lead	1.0	✓	✓	✓	Green
12	V6	Lead	1.0	✗	✓	✓	Green

Figure 24 - Non-Vector Leads

From this dialog the physician can modify all the properties of the channels that are being acquired, as well as varying the entrant's channel. The properties grid counts on the following 8 columns:

1. Number of order of the channel (de 1 a 12)
2. Input Channel: Indicates which derivation will be used in that entrance. Making a double click on any cell of this column will display a list containing all the possible leads to choose as entrance. The physician is free to choose any channel array at will.
3. Label: Description of the entrance derivation. This description can be modified any times along the study, registering all the changes and the time in which them happened in the review screen
To modify it, just do double click on the cell and insert the new description.
4. Gain: Modifies the amplitude of the derivation's signal. To modify the value you must do double click on the cell.
5. Visible: Shows or hides the derivation in the monitoring screen. This doesn't mean that the derivation is not being captured, it's that it isn't shown in the screen. Double click on the cell inverts its value.
6. Active: All the active derivations will response to the changes done from the Control Panel (See **Figure 16**). Double click on the cell inverts its value.
7. Clipped: Indicates if the derivation will be drawn clipped or not.. For signals with great amplitude may be needed to clip it not to interfere with the signals of the adjacent derivations. Double click on the cell inverts its value.
8. Color: Displays a gamma of colors to select for each derivation.

Once the changes are done the physician can:

- a. Do active the changes done: Click on the Apply button.
- b. Close the dialog without doing any change: Click on the Cancel button.

3. ASSIGNMENT OF THE CONTROL KEYS

When opened the monitoring window some of the keyboard keys have the following special functions:

➤ (RIGHT arrow): Increases the scanning speed in the monitoring and review screen.

➤ (LEFT arrow): Diminishes the scanning speed of both screens.

⬆ (UP arrow): Increases the amplitude of all channels.

⬇ (DOWN arrow): Decreases the amplitude of all channels.

HOME : Moves the signals on the review screen to the beginning of the study.

END : Moves the signals on the review screen to the end of the study.

PAGE UP : Moves the signals on the review screen 250 ms backwards.

PAGE DOWN : Moves the signals, on the review screen 250 ms forwards.

SPACE BAR : Freeze / Defreeze the signals on the monitoring screen.

Clicking on the image freezes at the end of the scanning. Making a double click freezes the image instantly.

Control + B : Enable / Disable the acoustic “BEEP” of the QRS.

IMPORTANT: The Data Acquisition Module should be cleaned regularly, using a cloth moistened in alcohol.

4. TECHNICAL SPECIFICATIONS

GALIX ECG-PS Data Acquisition Module (DAM-PS)

Input Amplifier

Frequency response:	0.05Hz±11% a 500Hz±5% @ -3dB
CMRR:	100dB min, @ DC to 60Hz
Background added noise:	1.1 µVrms max, @ 0.05Hz to 500Hz
Input Signal Span:	16.4mVpp±3% @ 10Hz
Electrode offset Tolerance:	300mV min.
Lead Input Impedance:	> 100 Mohm @ DC to 500Hz
Lead Bias Current:	1nA max
Reference Compensation:	Selectable for Limb or XYZ electrodes
Patient Connection:	10 leads (Limb+Chest) / 7 leads (Limb+XYZ), shielded cables with current limitation

Data Acquisition

Sampling Rate:	3000 samples per second per lead (1000 Sample/sec/lead, normalized)
Sampling Resolution:	0.25mV±3% (1 µV, normalized) @ 10Hz
Data Resolution:	16 Bits (14 Bits, normalized)
Analog Anti-Alias Filter:	500 Hz±5%, 3° order, Butterworth low pass
Modes:	12 Leads (Limb+Chest) / 9 Leads (Limb+XYZ)

Electrical

PC interface:	Full Speed USB 1.1, 12Mbit/s
Power consumption:	100mA max (supplied by Computer USB Port)
Patient Isolation:	2500V, 50pF max
Patient Leakage Current:	< 5uA (Patient Electrically Isolated)
Defibrillator Protection:	5 KV, 10 ms / 400 Joules

Physical

Size:	5.5" (140mm) x 2.5" (63mm) x 1.2" (31mm)
Weight:	0.5 lbs (230g), USB Interface Cable Included
Enclosure:	Water and Dust Proof, ergonomic design
Interface Cable length:	10ft (3m)
Color:	Off-White
External Material:	ABS (UL 94 HB)

Environmental

Operating Temperature:	50 to 110°F (10 to 45°C)
Storage Temperature:	-4 to 150°F (-20 to 65°C)
Operating Humidity:	5 to 95% relative, non condensing
Storage Humidity:	5 to 95% relative, non-condensing
Atmospheric Pressure:	700 to 1060 hPa

GALIX ECG-PS Software (running on PC)

Signal Processing

(Overall digital tolerance less than 0.1%)

Low Pass Filter:	150 Hz, FIR type
High Pass Filter:	0.05Hz / 0.15Hz / 0.5Hz, 3rd Order
Muscle Filter:	35Hz @ -3dB / 72Hz @ -40dB, Chebycheff Inv.
Baseline Drift Filter:	None / 0.5Hz
Line Suppression Filter:	None / 50Hz / 60Hz, 60dB min
Output Data Rate:	1000 Sps
Output Data Resolution:	14 Bits

Signal Analysis

(Calculated on the basis of the entire 10-sec recording)

Rate [bpm]: Heart Rate \pm 2% or 3bpm

ST-L [mV]: deviation of the ST segment from the isoelectric level in lead "L" \pm 0.1mm

STsl-L [mV/ms]: slope of the ST segment in lead "L" \pm 15%

Minimum PC requirements

SCREEN:

- Monitor: SVGA Color, 15" (Recommended: 17")
- Resolution: 1268 x 1024 / 1024 x 768 pixels, Non-interlaced, Color: 16 bits

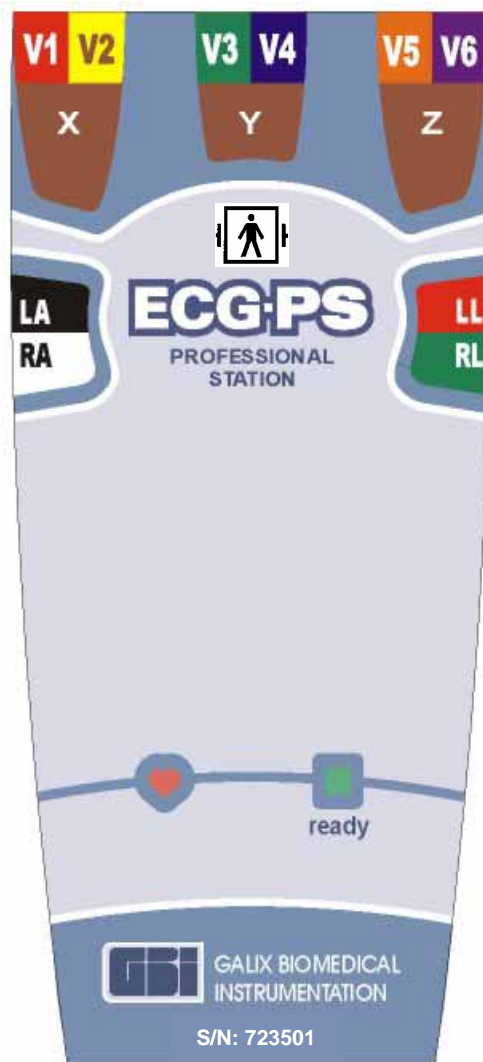
COMPUTER:

- Processor: PENTIUM III 700 MHz (or better)
- Hard Drive: 30 Gbytes (o better)
- RAM: 128 Mb
- I/O: Parallel, USB, Serial
- Accessories: Keyboard and Mouse
- Operating System: Windows98, Windows Me, Windows XP

Standard Accessories

- Five 2-lead fully shielded patient cable
- Four clamp electrodes (limb leads)
- Six suction electrodes (chest leads)
- One Installation CD
- One Hard-Lock protection key
- One Operation Manual

C



Front Label

5. WARRANTY

GALIX BIOMEDICAL INSTRUMENTATION

Limited Warranty

GALIX Biomedical Instrumentation provides to the original purchaser the following limited warranty from date of invoice.

All serialized parts	18 months
Accessories, i.e. patient	90 days
Cables, disposables	

GALIX Biomedical Instrumentation warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instrument when returned from the customer's facility prepaid to the factory. GALIX Biomedical Instrumentation will repair any component(s) or part(s) that is found to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser shall first notify GALIX Biomedical Instrumentation of the suspected defect. The instrument should be carefully packaged and shipped prepaid to:

GALIX BIOMEDICAL INSTRUMENTATION
Service Department
2555 Collins Avenue, Suite C-5
Miami Beach, FL 33140, U.S.A.
Tel.: (305) 534-5905 Fax : (305) 534-8222

Your instrument will be repaired in the shortest possible time and returned by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, act of God, or if the instrument has been serviced or modified by any person not authorized by GALIX Biomedical Instrumentation.

Equipment distributed by GALIX Biomedical Instrumentation such as, but not limited to personal computers and printers will carry the original equipment manufacturer's warranty and will not be warranted by GALIX Biomedical Instrumentation.

This limited warranty contains the entire obligation of GALIX Biomedical Instrumentation, and no other warranties expressed, implied or statutory are given. No representative or employee of GALIX Biomedical Instrumentation is authorized to assume any further liability, or grant any further warranties except as set herein.

GALIX BIOMEDICAL INSTRUMENTATION

2555 Collins Avenue, Suite C-5
Miami Beach, FL 33140, U.S.A.
Tel.: (305) 534-5905 Fax : (305) 534-8222
E-mail: info@galix-gbi.com